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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,086

06/21/2005

Philip James Gunning

94090

9264

24628

7590

12/31/2007

WELSH & KATZ, LTD  
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CHICAGO, IL 60606

EXAMINER

JARRELL, NOBLE E

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

12/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,086	<b>Applicant(s)</b> GUNNING ET AL.	
	<b>Examiner</b> NOBLE JARRELL	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/19/07;5/2/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Current Status of 10/531086***

1. Claims 1-20 are currently pending in the instant application and are being examined in the current office action.

### ***Information Disclosure Statement***

2. The information disclosure statements filed 3/19/2007 and 5/2/2007 fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "derivative" in the claims refers to esters and salts (page 5, lines 14-22). At which position is the ester attached to the sapogenin? Applicants show an ester at the 3-position on page 9 in the compound smilagenin benzoate, but the ester as it is claimed currently could be attached at any point on the molecule, not just the 3-position. In an analysis of claim 13 (and the perceived intended structure), the ester could be at any one of 6 points of attachment.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiebe et al. (*Steroids*, **1985**, 45(1), 39-51, cited in IDS) in view of March (*Advanced Organic Chemistry*, **1992**, 360-62). Wiebe et al. teach the conversion of 5 $\alpha$ -3-keto-dione 9 to compound 10 (3 $\alpha$ -hydroxy-5 $\alpha$ -pregnan-2-one with K-Selectride, which is potassium tri-sec-butylborohydride. The reaction only forms the 3 $\alpha$ -hydroxy epimer and is done in tetrahydrofuran (THF). Claims 10-11 are rendered obvious because March shows on table 10.13 that toluene and 1,4-dioxane are both solvents with similar  $E_T(30)$  values, which is a measure of polarity. Hence, THF is an obvious variant of toluene and 1,4-dioxane. Claim 12 is rendered obvious because 2-methyltetrahydrofuran and THF share the same core, and hence are obvious replacements of one another.

8. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gondos et al. (*Journal of the Chemical Society, Chemical Communications*, **1982**, 1239-40.

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Gondos et al. teach the reduction of 5 $\beta$ -andosterone-3,17-dione and 5 $\beta$ -pregnane-3,20-dione with K-Selectride. Claim 4 is rendered obvious because lithium is 1A element like potassium, and the replacement of one for the other will not affect the reduction. Claim 12 is rendered obvious because 2-methyl-tetrahydrofuran and THF share the same core structure, and hence the substitution of one for the other is obvious.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3, and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiebe et al. (*Steroids*, **1985**, 45(1), 39-51, cited in IDS). Wiebe et al. teach the conversion of 5 $\alpha$ -3-keto-dione 9 to compound 10 (3 $\alpha$ -hydroxy-5 $\alpha$ -pregnan-2-one) with K-Selectride, which is potassium tri-sec-butylborohydride. Claims 6-9 are anticipated because only the 3 $\alpha$ -hydroxy epimer is formed and the reaction is done in tetrahydrofuran (THF).

11. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tal et al. (*Tetrahedron*, **1984**, 40(5), 851-54). Tal et al. show the conversion of compound Vb to VIb with K-Selectride in THF (page 853, second column). Since only the 3 $\beta$ -hydroxy epimer was formed, claims 2 and 6-7 are anticipated. Claims 8-9 are anticipated because THF was the solvent used.

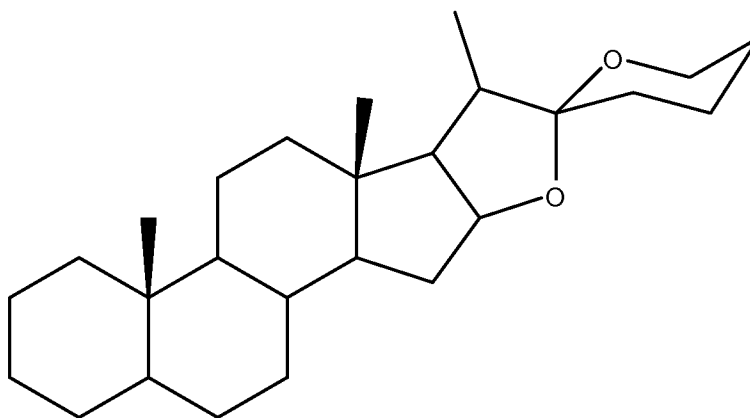
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12. Claims 1-4, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gondos et al. (*Journal of the Chemical Society, Chemical Communications*, **1982**, 1239-40. Gondos et al. teach the reduction of 5 $\beta$ -andosterone-3,17-dione and 5 $\beta$ -pregnane-3,20-dione with K-Selectride. Claims 1-2 and 6-7 are anticipated because the hydroxyl is formed and the major product is the 3 $\beta$  product. Claims 3-4 are anticipated because the reducing agent is K-Selectride. Claims 8-9 are anticipated because THF is the solvent used.

13. Claims 1, 5 8-9, and 15-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Tochtrop et al. (*Journal of Organic Chemistry*, **2002**, 67, 764-71). Tochtrop et al. convert compound 20a and 20b to compounds 21a and 21b, respectively in lithium tri-*tert*-butoxyaluminumhydride in THF (scheme 5, page 6768). Claims 15-17 are anticipated because the double bond with 5-atom is hydrogenated and only the 5 $\beta$ -hydrogen compound is formed with H<sub>2</sub> on Pd/C. The solvent being used is pyridine.

### ***Claim Objections***

14. Claim 13 is objected to because of the following informalities: the “desired sapogenin” of claim 13 seems incorrect, because this core structure cannot not include compounds of claim 14. The examiner translated the intended structure as the one shown below. Appropriate



### ***Allowable Subject Matter***

15. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/  
Examiner, Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner  
Art Unit 1624